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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

RE: Docket No. OOD-1598

Ladies and Gentlemen:

I am writing to request that the FDA make labeling of genetically engineered foods mandatory. Mandatory labeling is supported by overwhelming public sentiment and by the scientific literature, and is the only course consistent with FDA's statutory mandate to protect public health.

Your agency received more than 50,000 comments last year regarding genetically engineered foods. Most of these comments supported mandatory disclosure of bioengineered ingredients and processes. FDA responds that the comments "did not provide data or other information regarding consequences to consumers from eating the food." But in fact there is ample evidence that these foods are not "substantially equivalent" to non-genetically engineered foods.

Studies have shown that genetically engineered foods contain lowered levels of nutrients such as **isoflavones** and plant estrogens. They have been shown to have higher levels of Kunitz trypsin inhibitor, a known antinutrient and allergen. Genetically modified soybeans have caused allergic reactions in people with sensitivity to Brazil nuts (the source of the added gene). Genetically engineered foods contain antibiotic marker genes, and may compound the severe threat of antibiotic resistance in humans. Many genetically engineered foods contain built-in pesticides. These are not found in non-genetically engineered foods.

Last year, Monsanto admitted to finding 'unexpected gene fragments' in their genetically engineered soybeans. New proteins never before consumed by humans are being created and brought to market without any extensive tests being done to show that they are not causing allergies, cancer or other diseases. These experimental foods have not been adequately tested.

To date, FDA has a poor record of protecting the safety of consumers in the area of genetically engineered foods. The potential allergies created by the ingestion of **StarLink** corn completely escaped FDA scrutiny, until the EPA picked up the digestive problems associated with the product.

The Draft Guidance document lends credence to those who have accused FDA of being a pawn of the biotech industry. Not only does the proposal not require mandatory labeling of genetically engineered foods. The document goes further, raising a question whether manufacturers who choose not to use genetically engineered ingredients should be allowed to label their products as "GMO Free". If the agency decides to restrict the ability of a manufacturer to tell consumers which products are not

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genetically engineered, how can it pretend that public health concerns outweigh corporate profits in FDA's decision-making process?

Genetically engineered foods are required to be labeled in the European Union, Japan, Australia, New Zealand and many other countries. It is outrageous that the American public does not have comparable protection.

I have to eat. For reasons I consider more than adequate, I do not want to eat genetically engineered foods. Without mandatory labeling, I have no choice. Please use your regulatory authority for its intended purpose, and require that genetically engineered foods be labeled.

Thank you for your attention to these comments.

Sincerely,



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